

FORM PTO-1390 (REV 5-93)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY DOCKET NO. P564-9010	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				DATE: August 12, 1999	
				U.S. APPLN. NO. (IF KNOWN, SEE 37 CFR 1.5) 09/297,092	
INTERNATIONAL APPLICATION NO. PCT/EP97/06463		INTERNATIONAL FILING DATE 19 November 1997		PRIORITY DATE CLAIMED 19 November 1996	
TITLE OF INVENTION: COMPOUNDS WITH IMPROVED CARTILAGE-INDUCING AND/OR BONE-INDUCING ACTIVITY					
APPLICANT(S) FOR DO/EO/US: Michael PAULISTA, Jens POHL, Joachim PABST, Helmut HEIDE					
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. (THE BASIC FILING FEE IS ATTACHED)</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT articles 22 and 39(1).</p> <p>4. <input type="checkbox"/> A proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</p> <p>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input checked="" type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11. to 16. below concern other document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> Two assignment documents for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input type="checkbox"/> Other items or information: CHECK NO.</p>					

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U.S. APPLN. NO. (IF KNOWN, SEE 37 C.F.R. 1.50) 09/297,092	INTERNATIONAL APPLICATION NO. PCT/EP97/06463	ATTORNEY DOCKET NO. P564-9010 DATE: August 12, 1999
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17. <u>XX</u> The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search Report has been prepared by the EPO or JPO.....\$840.00 International preliminary examination fee paid to USPTO (37 CFR 1.482).....\$670.00 No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....\$760.00 Neither international preliminary examination fee (37 CFR 1.482) or international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....\$970.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)\$ 96.00	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">CALCULATIONS</td> <td style="width: 30%;">PTO USE ONLY</td> </tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>	CALCULATIONS	PTO USE ONLY										
CALCULATIONS	PTO USE ONLY												

ENTER APPROPRIATE BASIC FEE AMOUNT =	\$00																									
Surcharge of \$130.00 for furnishing the oath or declaration later than _ 20 _ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	\$00																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Claims</th> <th style="width: 20%;">Number Filed</th> <th style="width: 20%;">Number Extra</th> <th style="width: 20%;">Rate</th> <th style="width: 20%;"> </th> <th style="width: 20%;"> </th> </tr> <tr> <td>Total Claims</td> <td>13 - 20 =</td> <td>00</td> <td>X \$ 18.00</td> <td>\$00</td> <td> </td> </tr> <tr> <td>Independent Claims</td> <td>01 - 3 =</td> <td>00</td> <td>X \$ 78.00</td> <td>\$00</td> <td> </td> </tr> <tr> <td colspan="3">Multiple dependent claim(s) (if applicable)</td> <td>+ \$260.00</td> <td>\$00</td> <td> </td> </tr> </table>	Claims	Number Filed	Number Extra	Rate			Total Claims	13 - 20 =	00	X \$ 18.00	\$00		Independent Claims	01 - 3 =	00	X \$ 78.00	\$00		Multiple dependent claim(s) (if applicable)			+ \$260.00	\$00			
Claims	Number Filed	Number Extra	Rate																							
Total Claims	13 - 20 =	00	X \$ 18.00	\$00																						
Independent Claims	01 - 3 =	00	X \$ 78.00	\$00																						
Multiple dependent claim(s) (if applicable)			+ \$260.00	\$00																						
TOTAL OF ABOVE CALCULATIONS =	\$00																									
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).	\$00																									
SUBTOTAL =	\$00																									
Processing fee of \$130.00 for furnishing the English translation later the _ 20 _ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).	\$00																									
TOTAL NATIONAL FEE =	\$00																									
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property	\$00																									
TOTAL FEES ENCLOSED =	\$00																									
	Amount to be refunded	\$																								
	Charged	\$																								

a. _ A check in the amount of \$_ to cover the above fees is enclosed.
 b. _ Please charge my Deposit Account No. 14-1060 in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed.
 c. XX The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1060.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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 Reg. No. 22,980

PATENT COOPERATION TREATY

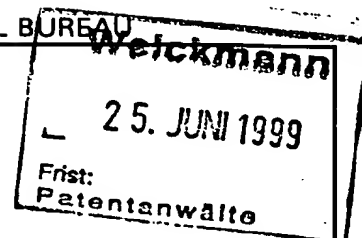
PCT
NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

From the INTERNATIONAL BUREAU

To:

WEICKMANN, H.
 Kopernikusstrasse 9
 D-81679 München
 ALLEMAGNE



Date of mailing (day/month/year) 09 June 1999 (09.06.99)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 15409P WO	
International application No. PCT/EP97/06463	International filing date (day/month/year) 19 November 1997 (19.11.97)
Applicant BIOPHARM GESELLSCHAFT ZUR BIOTECHNOLOGISCHEN ENTWICKLUNG VON PHARMAKA MBH et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

BR,CA,CN,GB,JP,KP,KR,NZ,PL,US


The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AP,EA,EP,AL,AM,AT,AU,AZ,BA,BB,BG,BY,CH,CU,CZ,DE,DK,EE,ES,FI,GE,GH,HU,ID,IL,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZW,OA

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Nestor Santesso  Telephone No. (41-22) 338.83.38
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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

11

Applicant's or agent's file reference 15409P WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP97/06463	International filing date (<i>day/month/year</i>) 19 November 1997 (19.11.1997)	Priority date (<i>day/month/year</i>) 19 November 1996 (19.11.1996)
International Patent Classification (IPC) or national classification and IPC A61L 27/00		
Applicant BIOPHARM GESELLSCHAFT ZUR BIOTECHNOLOGISCHEN ENTWICKLUNG VON PHARMAKA MBH		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 30 March 1998 (30.03.1998)	Date of completion of this report 29 January 1999 (29.01.1999)
Name and mailing address of the IPEA/EP European Patent Office D-80298 Munich, Germany Facsimile No. 49-89-2399-4465	Authorized officer Telephone No. 49-89-2399-0

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP97/06463

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

- ☐ the international application as originally filed.
- ☒ the description, pages 1-23, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.
- ☒ the claims, Nos. 1-13, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.
- ☒ the drawings, sheets/fig 1/1, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 97/06463

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-13	YES
	Claims		NO
Inventive step (IS)	Claims	1-13	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims	12, 13 see Box V	NO

2. Citations and explanations

- 1) US-A-4 596 574 describes an implant material that contains BMP as osteoinductive protein and a matrix material of calcium phosphate and that can be produced by coprecipitation (see column 5, lines 52-60 and Claims 7 and 8).

The subject matter of the present claims differs therefrom by the presence of a matrix material of calcium phosphate as component B, which itself possesses osteogenic activity.

This distinguishing feature has the effect of preventing harmful tissue reactions such as anachoresis of connective tissue or inflammations.

This was not obvious to a person skilled in the art, and so the subject matter of the claims involves an inventive step.

- 2) The PCT does not contain uniform criteria for evaluating whether the subjects of the present Claims 12 and 13 have industrial applicability. Patentability can also depend on the formulation of the claims. The EPO, for example, does not recognize

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 97/06463

as industrially applicable the subject of claims to the medical use of a compound; however, it may allow claims to the first medical use of a known compound and the use of such a compound in the manufacture of a drug for a new medical use.